REMARKS

Applicants have studied the Office Action mailed November 17, 2003. It is respectfully submitted that the application is in condition for allowance. Reconsideration and allowance of the pending claims in view of the following remarks is respectfully requested.

Objections to Amendment

The objection to amendment filed on August 18, 2003 as non-responsive in part has been corrected. All claims are presented as set forth above.

Rejection of claims 4, 8-9, and 24-29 under 35 USC §101 and §112, 1st paragraph:

The Examiner has rejected claims 4, 8-9, and 24-29 under 35 U.S.C.§101 and §112, 1st paragraph. In summary, the Examiner has stated that the claimed invention is not supported by either a substantial asserted utility or a well-established utility and, consequently, one skilled in the art would not know how to use the claimed invention.

In making these rejections, the Examiner states that there is no nexus between the claimed protein and therapeutics for humans, and that the specification as filed does not disclose or provide evidence that points to a property of the claimed protein such that another non-asserted utility would be established. The Examiner states that the polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required and, thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a "real world" context of use is required. The Examiner further asserts that the polypeptides do not (have) substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its functional nexus with human therapeutics. The Examiner states that, therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The Examiner further states that the disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed.

Applicants respectfully traverse this rejection based on the following remarks.

Contrary to the Examiner's assertions, the claimed isolated nucleic acid molecules, such as SEQ ID NOS:1 and 3, that encode a specified amino acid sequence, SEQ ID NO:2, and methods of using such nucleic acid molecules have several uses that meet the requirements of 35

U.S.C.§101 and the first paragraph of 35 U.S.C.§112. These, as well as the accepted state of the art view that such molecules have uses within the commercial marketplace in the drug development cycle, since they encode previously unidentified members of important pharmaceutical targets, establishes the utility of the claimed invention.

The utility requirement of a claimed invention requires that an invention must have a specific, substantial and credible utility. These requirements are defined in broad terms in cases such as Brenner v. Manson, 148 USPQ 689 (S. Ct. 1966) and the Utility Guidelines from the USPTO.

However, the notion that a recognized valuable addition to even entry points of the drug discovery cycle advances the art sufficient to establish a "usefulness" of a claimed invention should not be ignored. This is supported by previous case law (e.g., Nelson v. Bowler, 206 USPQ 881 (CCPA 1980)). Accordingly, the present invention, which is drawn to isolated nucleic acid molecules that encode a novel erg potassium channel (SEQ ID NO:2), has valuable commercial utilities in the drug discovery process by providing previously unidentified members of an important pharmaceutical target class. The present invention provides sufficient knowledge and information that is beneficial to the public, and provides sufficient guidance for researchers to use the claimed subject matter to develop disease treatments and/or diagnostics. It is well recognized that ion channels are among the most important target for drug action (see, e.g., pages 1-10 of the specification). The public disclosure of a new member of the erg potassium channel family through the patenting process clearly advances the art and augments the capabilities of biomedical researchers to combat illnesses.

The utility rejection raised by the Examiner also conflicts with the case Juicy Whip v. Orange Bang (Fed. Cir. 1999). Juicy Whip held that, in order to violate the utility requirement, an invention must be "totally incapable of achieving a useful result." The polypeptides and encoding nucleic acid molecules of the present invention are well known in the art to be valuable drug targets and therefore have readily apparent commercial utilities, such as for screening potential drug compounds, producing antibodies, developing hybridization probes and primers, etc. Therefore, the present invention is not "totally incapable of achieving a useful result." Instead, it is useful.

Applicants have provided sufficient guidance such that undue experimentation would not be required for one of ordinary skill in the art to comprehend the function and biological

significance of the disclosed polypeptides and encoding polynucleotides so as to be able to use the claimed invention. Applicants have characterized the polypeptide of SEQ ID NO:2 as a erg potassium channels. The functions and utilities of erg potassium channels are well established in the art and specifically recited in the specification. Erg potassium channels have substantial, real world uses and have been associated with specific disorders and are well known to be useful targets for human therapeutics. Thus, contrary to the Examiner's assertion, a functional nexus has been demonstrated between the protein of the instant application and human therapeutics.

For example, the following functions and utilities of erg potassium channels are specifically recited in the background section of the specification, particular in the section of the background entitled "Erg Potassium Channels" on pages 8-9.

Human erg (Herg) ion channels are inwardly rectifying potassium channels. Herg channels have properties consistent with the gating properties of eag, and other, outwardly-rectifying, S4-containing potassium channels, but with the addition of an inactivation mechanism that attenuates potassium efflux during depolarization. It is thought that these properties of Herg channel function are critical to maintaining normal cardiac rhythmicity. The molecular mechanism by which Herg ion channels protect the heart against inappropriate rhythmicity is described in Smith, P. L., *et al.*, "The Inward Rectification Mechanism of the HERG Cardiac Potassium Channel," 379 *Nature* 33 (1996) and in Miller, C. "The Inconstancy of the Human Heart," 379 *Nature* 767 (1996). (See page 8, last paragraph bridging to the first paragraph on page 9 in the Specification).

Because of the critical role played by the Herg gene in a well known human disease, and its use in the development of pharmacological therapies, it is important to determine whether additional Herg-like genes exist in humans that could also play an important role in LQT syndrome or in other diseases characteristic of abnormal ion channel function. Herg channels are also an important target for the development of new pharmaceuticals. For a further review of Erg potassium channels, see Shi *et al., J Neurosci* 1997 Dec 15;17(24):9423-32.(see page 9, third paragraph in Specification).

Such functions are quite specific for erg potassium channels and differentiate them from other proteins, including other eag, elk family. As such, these functions are specific enough to define a use for novel erg potassium channels and encoding nucleic acid molecules in the drug

discovery process and to enable one of ordinary skill in the art to use the claimed invention without undue experimentation.

Thus, it is clear that the disclosure of novel ion channel proteins, particularly novel erg potassium channels, satisfies a need in the art by providing important new compositions that are useful towards the prevention, diagnosis, and treatment of developmental, metabolic, and reproductive disorders, as well as various types of cancer, among other disorders. Consequently, one of ordinary skill in the art would recognize that novel ion channel receptors, particularly novel erg potassium channels, and encoding nucleic acid molecules, have substantial, "real world" uses that meet the requirements of 35 U.S.C.§101.

Thus, there is overwhelming evidence in the art to support the utility of novel ion channel, particularly novel erg potassium channels, and encoding nucleic acid molecules. Not all nucleic acid molecules, and actually a very limited number, of the 3 billion bases that make up the human genome will encode a protein for these and the other disclosed uses. These uses are quite specific for the ion channel protein family of proteins, and each is a specific composition of matter having substantial, specific and credible uses that the vast majority of other isolated nucleic acid molecules do not possess.

By placing a new member of the ion channel family, particularly a novel erg potassium channels, into the public domain through the patenting process, the present invention is not only a clear advancement over the prior art (a newly discovered protein/gene) but also enables significant advancement in medicine and further discovery. The Utility requirement cannot be used to contradict the reasons for the patent system, i.e., to encourage early disclosures of inventions so that others can benefit from, improve upon, and further develop such inventions. This is particularly important in medicine, wherein early disclosure of key inventions (such as new erg potassium channels protein and encoding nucleic acid molecules) is needed to facilitate the early development of new therapies and diagnostics to treat illnesses.

The grant of a patent to the claimed isolated nucleic acid molecule and the resultant disclosure of the nucleic acid and protein sequences to the public will certainly shorten the process for medical researchers to discover other novel uses for the present nucleic acid molecules which encode ion channels. One example disclosed in the specification is that the present nucleic acid molecules can be used to produce protein targets for identifying agents that bind to the protein targets and modulate protein function. Such agents that bind to a protein

target and modulate cellular processes such as signal transduction can subsequently be developed and refined for use in mammalian therapeutic applications. All of this later discovery and refinement will be done using the presently claimed material. These uses are clearly commercial and substantial uses that are specific for a very limited number of proteins/nucleic acid molecules.

In addition to serving as targets for developing molecular probes and therapeutic agents, the disclosed uses of the claimed nucleic acid molecules as probes, primers, and chemical intermediates, particularly in biological assays, is sufficient to satisfy the requirements of 35 USC §101 and §112. The claimed invention is directed to nucleic acid sequences, such as SEQ ID NOS:1 and 3, that encode an ion channel with a specified amino acid sequence (SEQ ID NO:2). Exemplary uses of the nucleic acid sequences are clearly recited in the specification on, for example, pages 37-56. Among the examples, the nucleic acid molecules are useful as hybridization probes for messenger RNA molecules, transcript/cDNA molecules, genomic DNA, and variants thereof. An expression vector comprising the nucleic acid sequences can be constructed that expresses the ion channel. Such uses are specific for the claimed nucleic acid molecules, and the products of such uses will be clearly different (and hence specific for the claimed molecules) than what would be produced using a different nucleic acid molecule for the same purpose.

In view of law and fact, the utility standard interpreted by the USPTO guidelines is too high. The commercial value of previously unidentified members of the ion channel family, particularly novel erg potassium channels, members of which are well known in the art to be commercially valuable drug targets, should be sufficient to satisfy the utility requirement. Therefore, applicants respectfully request that the Examiner withdraw the rejections.

Conclusion

Claims 4, 8-9, and 24-29 remain pending.

In view of the above remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3628 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,

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